K110547

Exactech® Optetrak® Logic™ PSC Tibial Insert
Special 510(k) – 510(k) Summary of Safety and Effectiveness

APR 14 2011

Sponsor: Exactech® Inc.
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Gainesville, FL 32653

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FDA Establishment Number 1038671

Contact: Patrick Hughes
Regulatory Affairs Specialist

Date: April 8, 2011

Trade or Proprietary or Model Name(s):
Exactech® Optetrak® Logic™ PSC Tibial Insert

Common Name:
Cemented Total Knee Prosthesis

Classification Name:
21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Class II.

Product Code: JWH – prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer.

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K093360	Optetrak Logic Total Knee System	Exactech, Inc

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Indications for Use:
The OPTETRAK Logic Total Knee System is indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

In the USA, the OPTETRAK Logic Total Knee System is indicated for cemented use only.

Device Description:
The proposed Optetrak Logic PSC Tibial Insert devices represent modifications to existing Optetrak Logic Total Knee System components (K093360). Both proposed and predicate devices are made from the same materials using the same processes and are compatible with the same Optetrak Logic tibial trays and femoral components. The proposed Logic PSC devices combine the articulating geometry and locking features of predicate Optetrak Logic posterior stabilized inserts with a central spine that is slightly thicker in the medial/lateral dimensions, intended to provide surgeons with an option for treating patients with minor ligament laxity by introducing 2°-3° more varus/valgus constraint than the predicate.

The proposed and predicate devices have the same intended use and basic fundamental scientific technology and share the following similarities:

- the same indications for use
- similar design features
- the same shelf life
- are packaged and sterilized using the same materials and processes.

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Performance Data

Table 1 shows performance data provided, cited, or referenced in this submission to support a conclusion of substantial equivalence:

Table 1: Optetrak Logic PSC Tibial Insert Performance Data

Evaluation	Activities Performed
Logic PSC tibial spine shear strength	• Review of predicate designs for clinical performance and resistance to shear forces • Engineering drawing comparison of Logic PSC spine dimensions to predicate designs with successful clinical performance
Logic PSC/mating femoral component compatibility	• Cadaver laboratory assessment • Review of predicate designs for clinical performance • Engineering drawing comparison of Logic PSC dimensions to predicate designs that successfully mate with the same components
Logic PSC varus/valgus constraint	• Cadaver laboratory assessment • Engineering drawing comparison of Logic PSC dimensions to predicate designs that successfully mate with the same components
Logic PSC internal/external constraint	• Cadaver laboratory assessment • Engineering drawing comparison of Logic PSC dimensions to predicate designs that successfully mate with the same components
Logic PSC tibial spine/mating femoral component clearance	• Review of predicate designs for clinical performance • Engineering drawing comparison of Logic PSC spine dimensions to predicate designs with successful clinical performance

Substantial Equivalence Conclusion:

Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Optetrak Logic PSC Tibial Insert devices are substantially equivalent to cleared predicate Optetrak Logic posterior stabilized tibial insert devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Mr. Patrick Hughes
Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

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Re: K110547
Trade/Device Name: Exactech Optetrak Logic PSC Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: February 23, 2011
Received: March 24, 2011

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak® Logic™ PSC Tibial Insert
Special 510(k) – Indications for Use

510(k) Number: K110547

Device Name: Exactech® Optetrak® Logic™ PSC Tibial Insert

INDICATIONS

The OPTETRAK Logic Total Knee System is indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

In the USA, the OPTETRAK Logic Total Knee System is indicated for cemented use only.

Prescription Use ___X___ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110547